

LAW OFFICES

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PATENTS  
 TRADE MARKS  
 COPYRIGHTS  
 UNFAIR COMPETITION

STEVEN E. KAHM  
 KIMBERLY S. ZILLIG  
 KEVIN W. CYR

March 10, 2000

Our Case Docket No. 20000018.ORI

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

## BOX PATENT APPLICATION

The Commissioner of Patents and Trademarks  
 Washington, D. C. 20231

Sir:

Enclosed herewith for filing is the patent application of inventor, CLAUDE TIHON, for "FEMALE INCONTINENCE PREVENTION DEVICE" together with the following:

- (1) One copy of five (5) sheets of informal drawings; and
- (2) The Declaration, Power of Attorney and Petition executed by the inventor; and
- (3) One executed Verified Statement Claiming Small Entity Status - Small Business Concern; and
- (4) An Assignment to CONTICARE MEDICAL, INC., executed by the inventor; and
- (5) The filing and recording fees are calculated as follows:

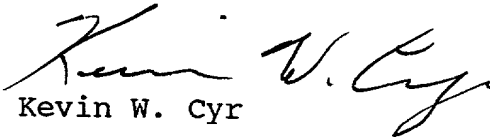
Basic filing fee	\$ 345.00
Total number of claims in excess	
of 20, times \$9.00 . . . . .	\$ 0
Number of independent claims,	
minus 3, times \$39.00 . . . . .	\$ 0
Surcharge fee (\$130.00) for filing of	
multiple dependent claim(s) . .	\$ 0
Recording fee for assignment	\$ 40.00
Total	\$ 385.00

A check in the amount of \$385.00 is enclosed to cover the filing and recording fees thereon.

The Commissioner is authorized to charge any fees or refund any overpayment under 37 C.F.R. 1.16 and 1.17 which may be required by this paper to Deposit Account No. 08-1265.

Yours very truly,

NIKOLAI, MERSEREAU &amp; DIETZ, P.A.

  
 Kevin W. Cyr

KWC/acl

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 jc781 U.S. PTO

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09522486-0310000



PATENT APPLICATION

ATTORNEY DOCKET NO. 20000018.ORI

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re App : CLAUDE TIHON

For : FEMALE INCONTINENCE PREVENTION DEVICE

\_\_\_\_\_

**VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS (37 CFR 1.9(f) and 1.27(c)) - SMALL BUSINESS CONCERN**

I hereby declare that I am

- ( ) owner of the small business concern identified below:  
(X) an official of the small business concern empowered to act on behalf of the concern identified below:

ContiCare Medical, Inc.  
A Corporation of Minnesota  
7680 Golden Triangle Drive  
Eden Prairie, MN 55344  
A Small Business Concern.

I hereby declare that the above-identified small business concern qualifies as a small business concern as defined in 13 CFR 121.12, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees to the United States Patent and Trademark Office, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention entitled "FEMALE INCONTINENCE PREVENTION DEVICE" by inventor, CLAUDE TIHON, described in the specification filed herewith.

If the rights held by the above-identified small business concern are not exclusive, each individual, concern or organization having rights in the invention is listed below\* and no rights to the invention are held by any person, other than the inventor, who would not qualify as an

[illegible]

independent inventor under 37 CFR 1.9(c) if that person made the invention or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d), or a nonprofit organization under 37 CFR 1.9(e). \*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27).

NAME

ADDRESS

( ) Individual ( ) Small Business ( ) Nonprofit Organization

NAME

ADDRESS

( ) Individual ( ) Small Business ( ) Nonprofit Organization

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate (37 CFR 1.28(b)).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this Verified Statement is directed.

NAME OF PERSON SIGNING:

TITLE OF PERSON IF OTHER THAN OWNER:

ADDRESS OF PERSON SIGNING:

SIGNATURE Claude M. Pres & CEO DATE 3/9, 2000.

## FEMALE INCONTINENCE PREVENTION DEVICE

### FIELD OF INVENTION

The present invention relates generally to incontinence prevention devices,  
5 and more particularly to an incontinence prevention devices having a non-concentric retention structures.

### BACKGROUND OF INVENTION

Many adults suffer urinary incontinence although urinary incontinence is  
10 more common in women than in men. The increased frequency in women is due primarily to the laxity of the bladder support structures resulting from pregnancy and aging. Surgical correction is possible in some cases, but surgery is invasive, costly and dangerous. Urethral incontinence prevention devices, such as for example catheters, plugs and other similar devices, in most cases offer a better solution but  
15 can be cumbersome to use, can be expelled during bowel movements, and are typically relatively expensive to manufacture.

There are a wide variety of incontinence prevention devices available, including: catheters that have lumen for urine to flow through; valved catheters; plugs that prevent the flow of urine until the plug is removed; and cylindrical  
20 supports against which the sphincter seals the urethra to prevent the flow of urine. Foley catheters are one type of commonly used catheter. Foley catheters are essentially elongated tubes. They are placed in the urethra to drain urine through the central lumen. An inflatable balloon is included near the distal end of the tube serves

as a retention structure. When inflated, the balloon holds the catheter in place. The proximal end of a Foley catheter typically has two ports: a drainage port to drain urine from the bladder and a balloon inflation port to inflate and deflate the balloon. The drainage port creates a permanent opening between the bladder and outside environment. Because the bladder is continuously emptied, the bladder's dome continuously rests on the tip of the catheter above the retention balloon causing compression, irritation and erosion of tissue as well as other tissue problems. Therefore, a need exists for a retention structure that does not protrude into the bladder such that it contacts the bladder's dome.

Plugs totally block the flow of urine. Therefore, the plugs typically require removal for the user to urinate. After removal, the old plug is not sterile and a new sterile plug must inserted into the urethra. Plugs' retention structures are typically cumbersome to operate and traumatic to the tissue. Thus, improper use can lead to irritation and infection from tissue traumatization. Further, the retention devices on the plugs are typically fluid filled and therefore relatively complex to manufacture. Therefore, a need exists for an incontinence prevention device that provides an atraumatic and simple means for insertion and removal and further reduces manufacturing costs.

Further, some urethral incontinence devices include open loop or pigtail type retention structures. These devices may be expelled when a user tenses the abdomen, such as when a user bears down during a bowel movement, because of a phenomenon called bladder neck drop often associated with incontinent female patients. With bladder neck drop, the bladder neck extends downward to encompass

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at least a portion of the urethra. The open loop type retention structures are thought to drop into the downward extension and thereafter could be entrapped in the urethra rendering it quasi-rectilinear as the bladder neck resumes its original shape. The improperly positioned device no longer functions properly and the quasi-rectilinear bladder retention structure can no longer maintain the device at its proper location permitting the user to later expel the device. Therefore, a need exists for an incontinence prevention device having a retention structure that maintains its appropriate position within the bladder neck regardless the physical forces acting on it, and can recover after momentary bladder neck drop.

10 In addition, typical incontinence prevention devices require, at least to some extent, that a proximal end extend from the urethral meatus. The proximal ends tend to scatter urine droplets during urination. The scattering of urine is inconvenient and unsanitary. Therefore, a need exists for a catheter that permits a directed stream of urine.

15 The present invention meet these needs and provides additional improvements and advantages that will be recognized by those skilled in the art upon review of the following description and figures.

## SUMMARY OF THE INVENTION

20 The present invention further provides an incontinence prevention device that is simple and inexpensive to construct and easy to use. The incontinence prevention device of the present invention includes a shaft and a retention structure. The retention structure is configured as a closed loop non-concentrically disposed about a





## BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 illustrates a perspective view of a urethral catheter showing a first embodiment of the retention mechanism;

5 Fig. 2 illustrates a left end view of the urethral catheter of Fig. 1;

Fig. 3 illustrates a perspective view of a urethral catheter showing a second embodiment of the retention mechanism;

Fig. 5A illustrates a side view of a stylet;

10 Fig. 5B illustrates a side view urethral catheter of Fig. 1 with a stylet partially inserted into the urethra measuring device; and

Fig. 5C illustrates a side view urethral catheter of Fig. 1 with a stylet fully inserted into the urethra measuring device.

## DETAILED DESCRIPTION OF THE INVENTION

15 The present invention is applicable to a variety of devices that are maintained in the urethra. The invention is described in the context of an incontinence device for a woman's urethra for exemplary purposes. The appended claims are not intended to be limited to any specific example or embodiment described in this  
20 specification. It will be understood by those skilled in the art that the present invention may be used in related medical applications including but not limited to incontinence prevention devices, obstruction relief devices, drainage devices; or other similar devices which require retention in a lumen. Further, in the drawings

described below, the reference numerals are generally repeated where identical elements appear in more than one figure.

Fig. 1 illustrates an embodiment of an incontinence prevention device 10 in accordance with the present invention. Device 10 includes a shaft 12, a retention structure 14 and a proximal retention structure 15. Device 10 may further include a lumen 18, shown in Fig. 2. Device 10 is typically circular in cross-section although other shapes such as oval that allow the sphincter to sealably contract against the catheter's outer surface may also be used. Device 10 is typically composed of a flexible biocompatible material such as silicone, silastic, polyurethane, polyethylene, polyimide, PTFE, ETFE, or other materials or combinations of materials known to those skilled in the art. Typically, the material used has a durometer shore hardness of between about 30 and 95 shore A. In addition, device 10 may be coated with a lubricious material, such as a hydrogel, to allow for easier insertion and reduced irritation.

Shaft 12 is typically configured as a semi-rigid region of device 10 typically having a shape suitable for placement in the urethra. Shaft 12 is further configured to have sufficient rigidity for sphincter muscles to contract against it so as to substantially stop the flow of urine from a user's bladder. Shaft 12 may also include an orientation marking 38, shown in Figs. 5B and 5C and discussed below. The orientation marking may either be visible, for example a line or dot, or tactile, for example a crevice or dimple. Shaft 12 typically has a diameter of around 8 French to correspond with an appropriate size for insertion in an adult female's urethra. The device can be made with various other diameters ranging from between about 5 to 16



structure slips below the neck and into the urethra, there is a tendency for the retention structure to be forced back into the bladder as the bladder neck and/or urethra resume their original orientation. Typically, a device having a retention structure in accordance with the present invention is capable of maintaining the catheter's position regardless of the forces typically encountered. However, the device may be removed by simply pulling on the proximal end with sufficient force to collapse the retention structure.

The retention structure may be substantially circular, as shown in Fig. 2, or may have various shapes appropriate for holding device 10 within the urethra that will be recognized by those skilled in the art. The retention structure is configured to be collapsible for insertion through the urethra and to regain its shape after insertion once in the bladder. After insertion, the retention structure has sufficient rigidity to hold the retention structure within the urinary bladder. To retain its shape, the retention structure may include an internal wire or be composed of a material with sufficient memory to regain the loop configuration.

In addition, Fig. 2 shows lumen 18 extending through the proximal end of shaft 12.

Fig. 3 shows an alternative embodiment of the retention structure. In the embodiment of Fig. 3, retention structure 14 includes a protuberance 22 projecting from the loop. In addition and as discussed in more detail below, a segment 21 may be attached to shaft 12 to form the loop and to provide protuberance 22. Protuberance 22 forms a smaller leading tip for easier insertion and helps to maintain the incontinence prevention device on a stylet during insertion. To facilitate this,

protuberance 22 typically includes a lumen that is coextensive with lumen 18 of shaft 12. That is, lumen 18 extends from a proximal end incontinence prevention device 10 to a distal end 26. Typically, the lumen does not extend through distal end 26 but only to a point immediately proximal to distal end 26. This configuration prevents the flow of urine through the lumen. Alternatively, the incontinence prevention device may have the lumen extending through distal end 26 to allow fluid flow through the lumen as required for some applications. When the retention structure includes a portion of the shaft, a segment 21 is typically provided to complete the loop comprising retention structure 15. Segment 21 is typically attached at one end to a first location proximate to distal end 26 of shaft 12 and, at the segment's other end, to a second location along the shaft closer to the shaft's proximal end so as to form a loop. Typically, the length of segment 21 and the positions for its attachment are selected so as to permit the loop to assume an appropriate configuration for insertion into the urethra and subsequent reformation into a loop when in the bladder. .

Shaft 12 and segment 21 may be configured to appear as a single unit for insertion. That is, when you straighten out the loop the two elements have the appearance of being one element. One such configuration may include configuring segment 21 as a horseshoe defining a cavity 23, as shown in cross-section in Fig. 4. Shaft 12 is then shaped to be received within cavity 23. When the loop is collapsed, cavity 23 receives shaft 12 and the retention structure appears as one element instead of a separate segment 21 and shaft 12. The actual circumference of the retention structure is therefore reduced making it physically easier to insertion and less

traumatic on the patient. In addition, the thinner appearance would tend to be less intimidating to a patient.

The shaft and retention structure may be composed of a uniform material or may be composed of layers of material to confer the desired characteristics. When layered, the structure may include, for example, an inner layer of polyurethane surrounded by an outer layer of silicone or other combinations that confer desired characteristics. For example, the layered structures may be formed by inserting a polyurethane tube inside a silicone sleeve. The fit between the polyurethane tube and silicone sleeve is such that their contact minimizes slippage between the two. To develop sufficient contact, the silicone sleeve is typically soaked in a suitable solvent to swell the sleeve. The polyurethane tube is then inserted into the sleeve. As the solvent evaporates, the silicone sleeve contracts against the polyurethane tube. Typically, only the shaft is provided with such a silicon sleeve.

Using the above method of manufacture, the polyurethane tube holds the structure together while the silicone provides an appropriate surface for the sphincter to contract against. In addition, the retention structure may be integral with the shaft or formed independent of the shaft. When integral, device 10 may be formed from a single tube having its distal end wrapped around and secured to the tube to separately define the shaft and the retention structure. When formed independently, the retention structure may have a different shape and physical characteristics than the shaft.

The method of using a incontinence prevention device in accordance with the present invention is best understood with reference to Figs. 5A, 5B and 5C. The

figures illustrate a method of linearizing a device 10, as shown in Fig. 1, for insertion into the urethra. Fig. 5A shows an insertion tool 30 having a handle 32 attached to a stylet 34. Handle 32 is not required but is typically provided for better control of the catheter during insertion. Stylet 34 is composed of a material, typically a metal wire, having sufficient rigidity to facilitate the insertion of the catheter into the urethra. Stylet 34 is typically sized to fit within lumen 18 of device 10. In use, stylet 34 is inserted into shaft 12 through lumen 18 at the shaft's distal end, as shown in Fig. 5B. Stylet 34 is advanced into shaft 12 through lumen 18. Once the stylet's distal end reaches retention structure 14, retention structure 14 assumes a conformation allowing insertion through the urethra, as shown in Fig. 5C, due to forces conferred by stylet 34. At this point, lubrication is typically applied to device 10. If the device is hydrogel coated, the device is lubricated simply by moistening the material. Alternatively, a water-soluble lubricant, like K-Y Jelly, or other suitable lubricant may be applied to the catheter's surface. In the embodiment shown, stylet 34 is typically advanced until retention structure 14 collapses in on itself due to the rigidity of the stylet and the tension exerted between the distal tip of stylet 30 and the point 36 where the loop attaches to shaft 12. Thus, insertion of the stylet renders urethral catheter 14 substantially rectilinear so as to allow insertion into a urethra. Retention structure 14 is then inserted into the urethra. Once retention structure 14 of the incontinence prevention device 10 is positioned within the urinary bladder, the stylet is removed allowing retention structure 14 to resume its original configuration. The proximal end of device 10 is then manipulated, if necessary, to properly orient non-concentrically configured retention structure 14

adjacent to the bladder neck within the patient. The orientation of retention structure 14 may be reflected by reference to orientation marking 38 on shaft 12. Thus, for example, when orientation marking 38 is oriented ventrally, retention structure 14 is properly oriented within the patient's bladder.

5



What is claimed is:

- 5

7. An apparatus, as in Claim 6, wherein the protuberance projects from a midpoint of the closed loop.

8. An apparatus, as in Claim 6, further comprising a lumen coextensive with the shaft and protuberance configured to receive a stylet.

9. An apparatus, as in Claim 8, wherein the lumen extends through a distal end of the protuberance.

10. An apparatus, as in Claim 8, wherein the lumen extends to a point proximal to a distal end of the protuberance.

11. An apparatus, as in Claim 6, wherein a segment of the retention structure defines a cavity to receive a portion of the retention structure.

12. A method treating incontinence, comprising:
- providing an apparatus including a shaft and a retention structure,  
wherein the retention structure is configured as a closed loop non-  
concentrically disposed about a longitudinal axis of the shaft;
- 5 rendering the retention structure substantially rectilinear;
- inserting the rectilinear retention structure through a urethra into a  
bladder;
- reforming the retention structure into a closed loop non-concentrically  
disposed about a longitudinal axis of the shaft; and
- 10 positioning the retention structure adjacent the neck of the bladder with  
the non-concentrically disposed retention structure in a predetermined  
orientation
13. The method, as in Claim 12, wherein the apparatus further comprises a lumen
- 15 configured to receive a stylet, wherein the lumen is coextensive with the shaft and  
substantially coextensive with the retention structure.
14. The method, as in Claim 12, further comprising providing a stylet and
- wherein the stylet is inserted into the lumen in the apparatus to render the retention
- 20 structure substantially rectilinear.

## 10

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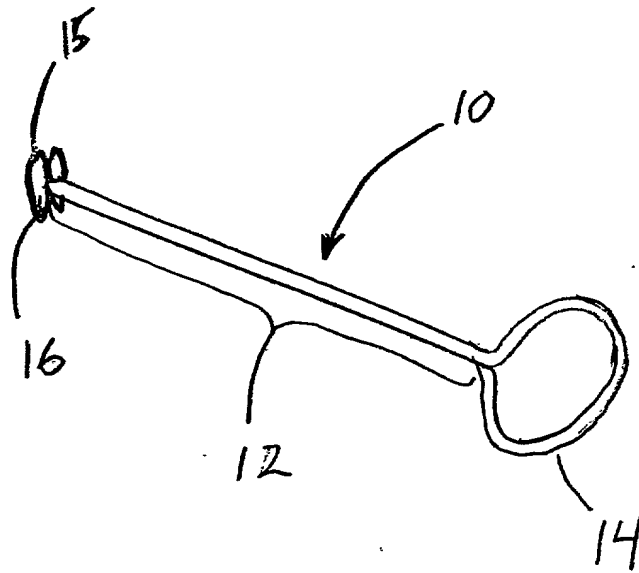


Fig. 1

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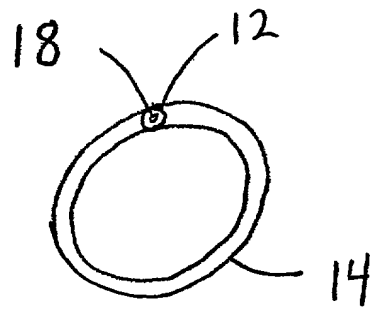
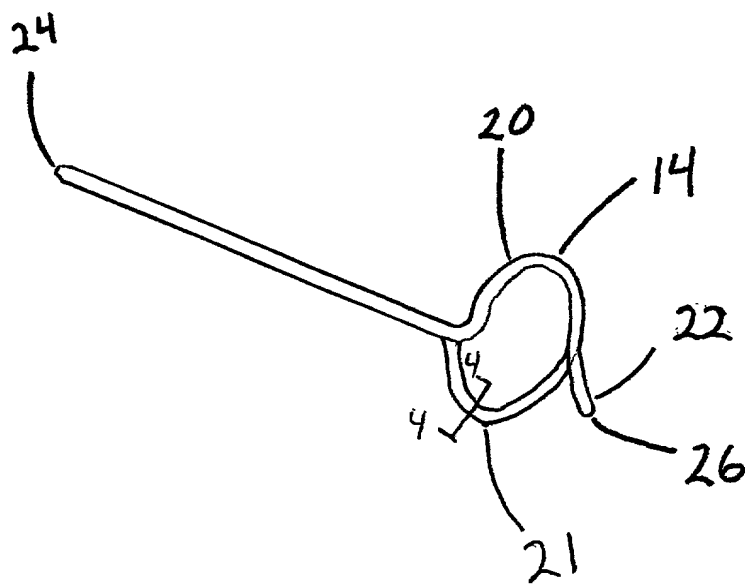


Fig. 2

Fig. 3



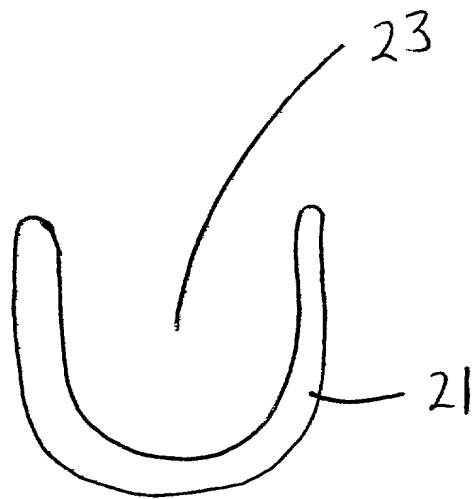
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Fig 4.





ATTORNEY FILE NO. 20000018.ORI

**DECLARATION, POWER OF ATTORNEY, AND PETITION**

I, CLAUDE TIHON, a citizen of the United States of America, residing at 11304 Bluestem Lane, Eden Prairie, Minnesota 55347, hereby declare that: my residence, post office address and citizenship are as stated above next to my name; and that I verily believe I am the original, first and sole inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled "FEMALE INCONTINENCE PREVENTION DEVICE", the specification of which is attached hereto.

I hereby state that I have reviewed and understand the contents of the specification including the claims as amended by any amendment specifically referred to in the Oath or Declaration.

I acknowledge the duty to disclose information which is material to patentability in accordance with Title 37, Code of Federal Regulations, Section 1.56.

I hereby appoint NIKOLAI, MERSEREAU & DIETZ, P.A., a professional association, consisting of the following attorneys/agents and the following attorneys/agents individually: Thomas J. Nikolai, Registration No. 19,283; Charles G. Mersereau, Registration No. 26,205; Paul T. Dietz, Registration No. 38,858; Steven E. Kahm, Registration No. 30,860; and Kevin W. Cyr, Registration No. 40,976 of 820 International Centre, 900 Second Avenue South, Minneapolis, Minnesota 55402-3813; Telephone No. (612) 339-7461, my attorneys/agents with full power of substitution and revocation to prosecute this application and transact all business in the Patent and Trademark Office connected herewith.

DECLARATION

	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	2037	2038	2039	2040	2041	2042	2043	2044	2045	2046	2047	2048	2049	2050	2051	2052	2053	2054	2055	2056	2057	2058	2059	2060	2061	2062	2063	2064	2065	2066	2067	2068	2069	2070	2071	2072	2073	2074	2075	2076	2077	2078	2079	2080	2081	2082	2083	2084	2085	2086	2087	2088	2089	2090	2091	2092	2093	2094	2095	2096	2097	2098	2099	2100	2101	2102	2103	2104	2105	2106	2107	2108	2109	2110	2111	2112	2113	2114	2115	2116	2117	2118	2119	2120	2121	2122	2123	2124	2125	2126	2127	2128	2129	2130	2131	2132	2133	2134	2135	2136	2137	2138	2139	2140	2141	2142	2143	2144	2145	2146	2147	2148	2149	2150	2151	2152	2153	2154	2155	2156	2157	2158	2159	2160	2161	2162	2163	2164	2165	2166	2167	2168	2169	2170	2171	2172	2173	2174	2175	2176	2177	2178	2179	2180	2181	2182	2183	2184	2185	2186	2187	2188	2189	2190	2191	2192	2193	2194	2195	2196	2197	2198	2199	2200	2201	2202	2203	2204	2205	2206	2207	2208	2209	2210	2211	2212	2213	2214	2215	2216	2217	2218	2219	2220	2221	2222	2223	2224	2225	2226	2227	2228	2229	2230	2231	2232	2233	2234	2235	2236	2237	2238	2239	2240	2241	2242	2243	2244	2245	2246	2247	2248	2249	2250	2251	2252	2253	2254	2255	2256	2257	2258	2259	2260	2261	2262	2263	2264	2265	2266	2267	2268	2269	2270	2271	2272	2273	2274	2275	2276	2277	2278	2279	2280	2281	2282	2283	2284	2285	2286	2287	2288	2289	2290	2291	2292	2293	2294	2295	2296	2297	2298	2299	2300	2301	2302	2303	2304	2305	2306	2307	2308	2309	2310	2311	2312	2313	2314	2315	2316	2317	2318	2319	2320	2321	2322	2323	2324	2325	2326	2327	2328	2329	2330	2331	2332	2333	2334	2335	2336	2337	2338	2339	2340	2341	2342	2343	2344	2345	2346	2347	2348	2349	2350	2351	2352	2353	2354	2355	2356	2357	2358	2359	2360	2361	2362	2363	2364	2365	2366	2367	2368	2369	2370	2371	2372	2373	2374	2375	2376	2377	2378	2379	2380	2381	2382	2383	2384	2385	2386	2387	2388	2389	2390	2391	2392	2393	2394	2395	2396	2397	2398	2399	2400	2401	2402	2403	2404	2405	2406	2407	2408	2409	2410	2411	2412	2413	2414	2415	2416	2417	2418	2419	2420	2421	2422	2423	2424	2425	2426	2427	2428	2429	2430	2431	2432	2433	2434	2435	2436	2437	2438	2439	2440	2441	2442	2
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